PROFICIENCY TESTING FOR GYNECOLOGIC CYTOLOGY

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CLIA '88

– Mandates periodic proficiency testing (PT) of individuals examining a gynecologic cytology specimens

– Not implemented nationally for past 16 years due to lack of an acceptable proposal

– CMS recently announced approval of PT administered by the Midwest Institute of Medical Education (MIME)

Proficiency testing: Gynecologic cytology

- Issues with PT as written in the regulations
  - Lack of field validation of slides in the initial round of testing

  - Scoring system inconsistent with 2001 practice guidelines issued by the American Society of Colposcopy and Cervical Pathology (ASCCP)

  - Currently available technologies such as computer assisted prescreening are not considered

Proficiency testing: Gynecologic cytology

- Field validation

  Perspective -

  – Cytologic screening is associated with a 70% decrease in the rate of cervical cancer

  – However, significant interobserver variability (lack of precision) in gynecologic cytology interpretations is well established

Gynecologic Cytology: Precision

Renshaw et al. 2003 - CAP Interlaboratory comparison program

Determined rates of exact match with reference interpretation for slides examined between 5 and 24 times

- Three expert cytopathologists at CAP had agreed that the cases were good examples and SILs were confirmed histologically

- 25745 responses on validated slides; 14353 on non validated slides

Gynecologic Cytology: Precision

- 29.7% of field validated and 28.6% of non-validated HSIL slides had a 100% exact match rate

- 11.8% of field validated and 18.3% of non-validated HSIL slides had <50% exact match rate

- HSIL was one the least reproducible/most difficult interpretations

Renshaw AA, Davey DD, Birdsong GG et al. Precision in gynecologic cytologic interpretation: a study from the College of American Pathologists Interlaboratory Comparison Program in Cervicovaginal Cytology. *Arch Pathol Lab Med*. 2003;127:1413-20.

Gynecologic Cytology: Precision

- Renshaw et al. 2005 - CAP Interlaboratory comparison program

  Determined rate of the field validation of slides selected as excellent examples of their diagnostic categories by three expert cytopathologists

- Overall, 19% of conventional smears and 15% of ThinPrep smears failed field validation

- >50% of unsatisfactory specimens failed to validate

Renshaw AA, et al Measuring the significance of field validation in the College of American Pathologists Interlaboratory Comparison Program in Cervicovaginal cytology: How good are the experts. *Arch Pathol Lab Med*. In press

Gynecologic Cytology: Precision

- Coleman, et al, 1997 – UK

  Reviewed results of bi-annual PT. (7 cycles)

  247 cytologists took the exam at least once

- Of 63 cytologists taking the exam 7 times, 7 failed one round despite scoring highly on the remaining rounds (6 had perfect scores in at least 5 rounds)

- 3 poor performers were identified

Gifford C, Green J, Coleman DV. Evaluation of proficiency testing as a method of assessing competence to screen cervical smears. *Cytopathology*. 1997;8:96-102.

Nagy GK, Collins DN. False-positive and false-negative proficiency test results in cytology. *Acta Cytol*. 1991;35:3-7.

Proficiency testing: Gynecologic cytology

- Use of unvalidated slides
  - Decreases the certainty with which individuals needing remediation can be identified
  - Increases the risk of falsely labeling competent individuals as needing remediation
  - Poor performers will be more accurately identified if the slides are field validated.

Proficiency testing: Gynecologic cytology
Scoring system for Technical Supervisors

Examinee's response: A   B   C   D

Correct response category:

A.. 10   0   0   0

B.. 5   10   0   0

C.. 5   0   **10**   **5**

D.. 0   -5   **5**   **10**

Proficiency testing: Gynecologic cytology

- ~20% of LSILs are associated with high grade histologic lesions (ALTS, CAP)

- ASCCP Guidelines - 2001
  - Colposcopy is the next step in patient management for both LSIL and HSIL interpretations

CONSENSUS GUIDELINES: Guidelines on Management of Women with Cytological Abnormalities.
http://www.asccp.org/consensus/cytological.shtml

Proficiency testing : Gynecologic cytology

- ## New technologies: Not provided for in current schema
  - ### Computer assisted identification of fields which may contain abnormalities

Parker EM, Foti JA, Wilbur DC. FocalPoint slide classification algorithms show robust performance in classification of high-grade lesions on SurePath liquid-based cervical cytology slides. *Diagn Cytopathol*. 2004;30:107-10.

Biscotti CV, Dawson AE, Dziura B, Galup L, Darragh T, Rahemtulla A, Wills-Frank L. Assisted primary screening with the ThinPrep imaging system. *Am J Clin Path. 2005;123:2*

Proficiency testing : Gynecologic cytology
SUMMARY

- Slides should be field validated

- Scoring system should correspond to contemporary practice guidelines

- Impact of new technologies should be taken into consideration

- Appropriate frequency of examination needs to be determined